CARDIOLINE®

ar2100adv

user manual

CE 0470

english

This User Manual has been prepared with the objective of giving the user all the information necessary to make the best use of the **CARDIOLINE® ar2100adv**.

General information

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CARDIOLINE® product support services

For any questions about a *CARDIOLINE* product:

- ✓ consult the documentation and other printed material included in the package;
- ✓ consult any guidelines available.

If you find no solution, you can obtain further information by contacting your *CARDIOLINE* supplier.

Before calling, check you have the available documentation to hand and the product nearby. It may also be necessary to supply the following information:

- ✓ serial number and product reference number, if available;
- ✓ type of hardware available, including any network hardware fitted;
- ✓ operating system used, for software products;
- ✓ exact contents of any error messages displayed;
- ✓ description of the operation being executed when the problem occurred;
- ✓ description of any action taken to solve the problem.

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1 Introduction

ar2100adv combines optimised performance in multichannel ECG recording with all the features of reliability, modularity, versatility and upgradeability that characterise the latest generation of **CARDIOLINE®** electrocardiographs.

ar2100adv is an electrocardiograph with dual power supply (mains and rechargeable internal batteries), which in the basic configuration will:

- ✓ record an ECG exam in automatic, manual and timed mode;
- ✓ reproduces the ECG signal on 210 mm paper in various formats thanks to high resolution thermal printer: 3, 6x1, 6x2, "Full Page 1" (3x4+R for 1 page), "Full Page 3" (3x4+3R for 1 page) and 12 channels;
- ✓ store the most recent recording in automatic mode and print additional copies.

Thanks to the flexibility of the software used and to the infrared interface, the **ar2100adv** can be adapted at any given moment to suit your individual requirements. The range of "*options*" offered is particularly generous and there are no restrictions or constraints, as the selection can be made either at the moment of purchase or later on at your clinic or surgery without having to interrupt day-to-day activity.

In just a few minutes, your **ar2100adv** can be equipped with:

- "memory option": storage of up to 40 full ECG exams, with no need to print out immediately on paper ("paper saving" mode);
- "ECG parameters option": automatic ECG parameter measurement program;
- "ECG signal interpretive option": a useful and dependable diagnostic support provided by the program;
- "arrhythmia option": a program enabling detection of arrhythmia events during continuous recording;
- "HRV analysis option": a program enabling detection of variations in heart rate;
- "PC archive option": for saving the exam to archive stored in a personal computer running CARDIOLINE software. The data upload to the PC is made by use of the wireless "IR" interface; no direct connection to the PC is required.
- "PC-ECG option": for real time display of the twelve leads on your computer screen to allow management of patient medical records and archiving of exams in digital format using CARDIOLINE software. The software has an optional module for automatic interpretation of the ECG signal.

For more information on available options, contact your selected dealer.

CONGRATULATIONS ON YOUR PURCHASE. Your new computerised electrocardiograph CARDIOLINE® has been designed and built in compliance with the applicable regulations in force at the time when et medical devices SpA, Cavareno (Trento) - ITALY drew up this manual. et medical devices operates in accordance with the requirements for quality management systems defined by EN ISO 9001: 2000 and EN ISO 13485: 2003 standards. The system is covered by a Nemko Certification AS (Cert. N. 800278). Your new electrocardiograph has also been built in compliance with the Medical Device Directive 93/42/EEC and is therefore marked by the relevant CE0470 mark.

1.1 How to read the manual

In order to ensure the **CARDIOLINE® ar2100adv** is operated in a safe and correct manner, and to appreciate its ease of use and high reliability, **the user instructions must be read carefully**.

This documentation describes the functions of your electrocardiograph including those provided by all the possible "options" available. It is therefore possible that some of the functions described may not be present in the model you have purchased. For details of the options, consult the "firmware configuration" chart that accompanies each individual appliance.

This symbol allows you to identify the functions **not** provided on all models, which must be requested specifically at the time of purchase.

This symbol allows you to identify the functional, behavioural and operational aspects that may be conditioned by the type of configuration selected during the step of *"Preparation for use: the menu"*.

When a given key is depicted in the body of a sentence or a paragraph, *press* the corresponding key on the device to perform the action.

The structure of this manual allows you to approach the use of the electrocardiograph according to your level of knowledge. If you have already had experience with **CARDIOLINE®** equipment, the initial fast-track part of each paragraph will allow you to begin working immediately. In the continuation of the paragraph, on the other hand, the single aspects of operation are discussed in more depth.

The manual gives detailed information on the use of the model **ar2100adv** in traditional ECG procedures, and an introduction to the use of particular functionalities involving interaction with software and a Personal Computer. For instructions on the use of the software applications for Personal Computer, consult the special online guides.

The quick guide to the electrocardiograph (at power-up the display shows the message " ? Press 1 ":

to obtain the printout) sums up the operations linked to the single commands presented in the manual.

Further information and clarifications can be requested directly from:
CARDIOLINE® - Supporto Prodotto
Strada Rivoltana Nuova, 53, I - 20060 Vignate (MI) ITALIA
e-mail: et.service@etmed.biz
tel. +39 02 95 05 181 fax: +39 02 95 66 013

1.2 Information and recommendations relating to safe use

- The electrical system used by the device must be in accordance with the standard in force.
- Always use the equipment according to the instructions in this manual.
- The device is equipped with a set of standard accessories. For reasons of safety, reliability and conformity with the Medical Devices Directive 93/42/EEC, use only original accessories or accessories approved by the manufacturer.
- The device is equipped with a special long-life thermal head writing system, which allows maximum writing precision. To avoid frequent and costly replacements and repairs, always use the original paper or paper approved by the manufacturer. The manufacturer will not accept liability for any damage to the device or any other adverse effect caused by the use of unsuitable paper.
- Do not subject the device to impact or excessive vibrations.
- Do not allow liquids to penetrate inside the device. If this should accidentally occur, have the device tested by an Authorised Assistance Centre to verify its functional efficiency, before using it again.
- Make sure that the value of the supply voltage corresponds to that indicated on the data plate of the device.
- If you are using the device in connection with others, ensure that: all connections are made by skilled persons; all connections comply with safety regulations; all other devices connected respond likewise to regulations. Non-compliance with regulations can cause physical harm to the patient connected and to the person operating the device. Should it be difficult to obtain the necessary information for assessing the risk of the individual connections, apply directly to the manufacturers concerned or avoid making the connections.
- In the event of other equipment being connected directly or indirectly to the patient, check for the possible risks caused by the sum of the leakage currents on the body of the patient.
- The device is protected against defibrillation discharges in accordance with IEC standard 601-1-25; to ensure that the signal is restored, use only original electrodes or electrodes responding to IEC and AAMI standards.
- If an electrosurgical scalpel is in use, the patient cable should be disconnected from the device.
- At all events, when defibrillators or high-frequency surgical devices are being used at the same time, it is essential to take the greatest care. If

there is any doubt when such devices are in use, disconnect the patient from the electrocardiograph temporarily.

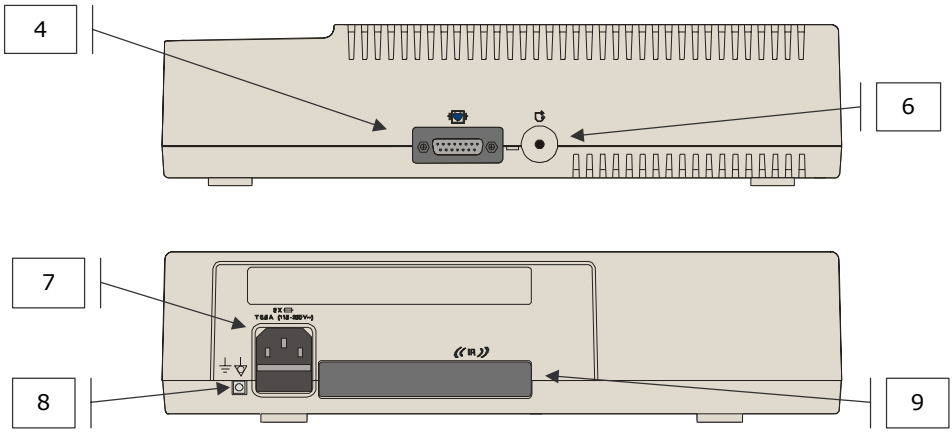
- The device recognises the impulses generated by a pacemaker and does not interfere with its operation, as prescribed by standards in use at the time of drafting this manual.
- Avoid exposing the equipment to extreme temperatures, excessive dust or dirt, and very salty or damp environments; observe the ambient conditions described in detail under the "*Technical specifications*" heading.
- Periodically check the efficiency of all accessories and of the device itself. Contact the Authorised Assistance Centre whenever the device seems to be operating irregularly. To prolong the life of your device, have it checked periodically by an Authorised Assistance Centre.
- **Warning**: The electrocardiograph can be used for intracardial applications.
- **Warning:** It is therefore necessary before activating the equipment, to make sure of the connection to ground (normally secured by the power supply cable). If grounding of the main electrical service is not certain, do not connect the device and use it powered only by the rechargeable internal battery.
- **Warning:** do not use the device in the presence of anaesthetics or volatile gases!
- **Warning:** devices for medical applications must be used only by persons who by virtue of training or practical experience are able to ensure maximum safety and effectiveness in operation. Operators must in any event read this manual carefully and familiarise themselves with the instrument before using it on a patient.
- **Warning:** the indications obtained using automatic interpreting programs or other diagnostic aids must be reviewed and countersigned by a qualified medical person!
- **Warning:** the device is provided with an IR interface for the transfer of data to other devices. The IR interface must not be masked, even accidentally, as this will adversely affect its capability and its operation, interrupting and preventing the correct flow of data.
- The manufacturer will acknowledge liability for the safety, reliability and functional efficiency of the device only if:
    - modifications and repairs are performed by the manufacturer or by an Authorised Assistance Centre;
    - the a.c. mains power supply of the building responds to current regulations;
    - the device is operated according to user instructions;
    - any accessories in use are those approved by the manufacturer.

1.3 The electrocardiograph

In order to simplify the installation and the use of your electrocardiograph, it is recommended that you become familiar with the component parts and with the logic of its operation.

Front view

Side view



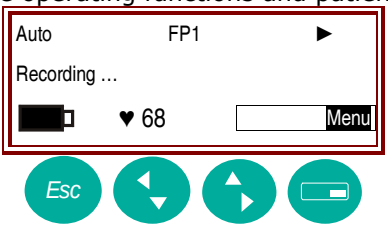
Parts, symbols and controls

1. Keyboard:

Function key	Messages & Symbols displayed / Associated LED	
on/ off		- LED on: device connected to mains power; internal battery charging
		- "full" symbol: battery charged - "part empty" symbol battery power less than 30% - "empty" symbol: internal battery flat; the device must be connected to the mains power for recharging
select start operating mode	⚠	- indicated electrodes not connected or insufficient contact; saturation
interrupt current operation; stop		
select operating mode	Auto	- Automatic recording
	Man	- Manual recording
	Personalised	- Recording mode selected in configuration phase ("Personalised mode")
select print format :	- Automatic mode: 3x1, 3x2, 6x1, 6x2, 12, Full Page 1, Full Page 3. - Manual mode: 3, 6, 12.	
a.c. mains and muscle interference filter		- filter on
	25	- paper speed 25 mm/s
	50	- paper speed 50 mm/s

select paper speed	5	-	paper speed 5 mm/s
select recording sensitivity		-	automatic sensitivity: the device optimises the ratio between n° channels and available space
	5	-	sensitivity 5 mm/mV
	10	-	sensitivity 10 mm/mV
	20	-	sensitivity 20 mm/mV
copy last recording			

2. Display: to manage operating functions and patient data



In normal operating mode:

- line 1: information on recording parameters selected;
- line 2: operating information and error messages;
- line 3: battery charge status, heart rate, menu;
- ▲▼◄► indicate the presence of additional menu options and information.
- Esc cancel operation, delete text, return to previous menu.
- scroll menus and information.
- Menu access and selection. Execute action highlighted on lower right of display (e.g.Select).

3. QWERTY alphanumeric keyboard for patient data management.

-

displays symbol map and special characters. to select. to copy symbol into text.
-
delete text.
-
confirm.

4. CF type patient cable connector protected against defibrillation as indicated by the symbol.
5. Paper compartment door.
6. Reset button : used to re-establish normal operating conditions in the event of an error that cannot be managed using the keyboard.
7. "Mains line" connector.
8. Equipotential earth connection / functional.
9. IR infrared interface.

2 Installation and initial preparation

This section describes the operations to be performed before using your new **CARDIOLINE® ar2100adv** electrocardiograph. Suggestions are given for "*selecting the installation site*" and "*recommendations for safe use in conformity with current statutory regulations*" are indicated. Also introduced are the operations involved in preparing the electrocardiograph for use, such as "*loading the thermal paper*", "*power supply"; "control and management of the rechargeable internal battery*", "*switching on and off*", "*the menu*", "*set-up*".

2.1 Selecting the installation site

Your electrocardiograph complies with European directives on electromagnetic compatibility. The absence of emissions damaging to radio and telecommunications transmissions is therefore assured, as also is protection from interference emitted by other systems and equipment Nevertheless, in order to protect your device from other equipments not in conformity with the aforementioned directives:

- avoid the use of mobile phones near the electrocardiograph;
- place the electrocardiograph as far as possible from electrical power lines and sources of static electricity. The ECG signal can be disturbed if the electrocardiograph is placed near sources of high voltage or electricity lines;
- avoid placing the electrocardiograph close to other diagnostic or therapeutic equipment (e.g. X-ray machines, ultrasound machines, electrically operated beds, etc.) that could be a source of excessive interference and ECG signal distortion;
- if it is impossible to position the electrocardiograph at a distance from other electrical equipment, switch the other equipment off while recording an ECG.

Also, to avoid the effect of ambient conditions when recording ECG:

- record in a room where the temperature is between 20 and 25 degrees Centigrade. This precaution prevents the patient from feeling cold, which could increase shivering and contribute to muscle tremor;
- record using the battery, disconnecting the device from the mains power supply. This avoids presence of mains power disturbance of the recorded ECG signal.

2.2 Loading the thermal paper

CARDIOLINE® ar2100adv is able to reproduce the ECG signal both on thermal paper in Z-fold packs with A5 or A4 perforations. Thermal paper in rolls with A4 perforations can also be used. No particular configuration procedure is required. To correctly load the different types of paper:

If using paper in packs:

a. Open the paper compartment.

b. Prepare a new pack and position it in the compartment. *Check that the red mark on the paper is on the upper left of the pack.*

c. Position the paper, centring it between the two paper guides. Close the cover, positioning the paper between the rubber roller and the device case.

If using rolls of paper:

d. Open the paper compartment and remove the "roll guide". To avoid losing the "guide", place it in a safe place. *If replacing an empty roll, retrieve the core before throwing away the empty roll.*

e. Insert the core in a new roll of paper and place in the paper compartment, fitting the pins into the guides provided. *Check that the black mark on the paper is on the upper part of the paper holder.*

f. Position the paper, centring it between the two paper guides. Close the cover, positioning the paper between the rubber roller and the device case.

Caution: *use only original thermal paper or paper approved by the manufacturer. The use of paper that does not respond to the manufacturer's specifications could jeopardise the correct operation of the device.*

2.3 Power supply; control and management of the rechargeable battery

Your electrocardiograph uses a dual power supply system: a.c. mains and a rechargeable lead battery.

The rechargeable battery is housed inside the device, and is protected against short circuits.

Caution: *before using the device, it is necessary to go through a complete cycle of recharging of the battery!*

Before connecting the electrocardiograph to the a.c. supply with the cable supplied, check that the mains voltage is the right voltage for the device.

Caution: *when the device is connected to the mains, the batteries are recharged automatically, even during use.*

To gain maximum benefit from the characteristics of the dual power supply system, follow the indications given below.

Recharging the battery

The battery must be recharged when the power indicator symbol is part

empty : the reserve charge is lower than 30%.

Connect the electrocardiograph to the mains: Led lit. Complete recharging of the battery requires at least 24 hours.

For longer life, the battery should be allowed to run down and recharged completely at least every two months.

A complete recharge allows the recording of up to 220 complete ECGs (automatic recording mode, 6 channel print format, speed 25 mm/s, complete with analysis, two A4 pages).

If the battery should be completely discharged (symbol), it is still possible to make an ECG recording by connecting the device to the a.c. mains supply.

The average life of the battery is more than 300 complete discharge/recharge cycles.

Warning: *do not dispose of a spent battery as ordinary refuse or litter. If the battery appears to need replacing, consult an Authorised Assistance Centre.*

Warning: *the device must be connected only to mains with earth connection, realised following the current regulations.*

2.4 How to switch on the electrocardiograph

for at least two seconds.

The display lights up. for at least two seconds. The display lights up.

Warning: *if the symbols and are displayed, internal power is insufficient and the battery must therefore be recharged by connecting the device to the mains (see heading "Power supply; ..."). The battery will recharge even if the device is in use.*

2.5 How to switch off the electrocardiograph

.

The display turns off. The settings for the last recording remain stored in the memory. To see the effect of switching off on the last automatic recording see "Copy an automatic ECG recording".

Warning: *switching off is not enabled 1. during the transmission of an ECG to a PC; 2. during the self-test routine; 3. if "set-up" mode is active. In these cases, first stop the device* *and then switch off.*

Auto power off

To conserve the battery charge, the electrocardiograph is provided with an auto power off function that will activate automatically, depending on the amount of power still available and on the operating mode selected. *The procedure is activated only after the current operation has been completed*.

- After 10 min. has elapsed without any key being pressed: reserve power > 30%.
- After 1 min. has elapsed without any key being pressed: reserve power between 15 and 30% .
- After 10 sec. have elapsed without any key being pressed: reserve power < 15% .

If the auto power off function is activated, last ECG recorded, if any, and the relative settings, will be held in the memory.

Auto power off is inhibited if:

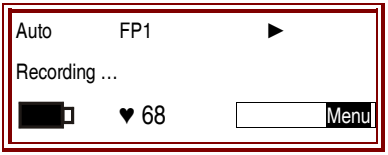
- a recording is in progress in ECG autotimer mode;
- a recording is in progress in PC-ECG mode;
- a recording is in progress in HRV mode;
- a recording is in progress in Arrhythmia mode;
- during the self-test routine;
- during "set-up";
- the device is connected to the mains.

3 Preparation for use: the menu

Navigating within the menu of your **ar2100adv**, there are options for intuitive personalization of the operating modes using the dedicated display keys.
To ensure your electrocardiograph can be operated taking advantage of its simplicity and versatility of use to the maximum, it is advisable to select the preferred set-up before the first recording is made.

3.1 How to access the menu

From the main page:



- to display the menu.
- to scroll through the menu items.
- to access the lower level menu or make a selection. Execute action highlighted on lower right of display (e.g. Select).
- to return to the previous level.

3.2 Structure of the menu

The menu is organised in four sections: "Personalised mode"; "ECG archive"; "Settings" and "Tools". The following tree layout of the menu illustrates the different levels of exploration possible, and the features that can be selected. Details on the single items are given in subsequent headings.

- *Personalised mode*
  - Paper Saving ☑
  - PC ECG ☑
  - Arrhythmia Monitor ☑
  - HRV analysis ☑
  - ECG autotimer
  - Arrhythmia Monitor ☑

- *ECG archive* ☑
  - View
    - PC archive
    - Print
    - Delete
  - PC archive
  - Print list
  - Clear
- *Settings*
  - Operation Profile
    - Patient data management
      - All / None
      - Patient ID.
      - First Name
      - Last Name 1
      - Last Name 2
      - Date of Birth
      - Sex
      - Height
      - Weight
      - Type
      - Blood Pressure
      - Medications
      - Notes
      - Ward/Dept.
    - Lead Sequence
      - Standard
      - Cabrera
    - Auto FP
      - Simultaneous
      - Sequential
    - FP Rhythm Leads
      - Change
        - Lead Selection
    - Configure analysis ☑
      - ECG parameters
        - Summary
        - ST amplitudes
        - Templates
      - ECG interpretation
        - Summary
        - Rhythm
        - Interpretation
        - Parameters
        - Templates
      - None
    - Configure Copy
      - Complete
      - ECG Only

- Analysis Only ☑
- Archive management ☑
  - Save
    - Automatic
    - On demand
    - None
  - Deleting
    - Manual
    - Automatic
- HRV analysis ☑
  - Duration: x
  - Lead
- Autotimer
  - No. Intervals
  - Duration of intervals: xxx
  - Print format
    - 12 leads
    - 3 leads
    - Lead Selection
    - 6 leads
    - Lead Selection
- Arrhythmia mode
  - RR Advance
  - RR Delay
  - Print Advance
  - Print Delay
  - Arrhythmia Monitor

- General
  - User Name
  - Device ID
  - Ward/Dept. Name
  - Date \ Time
  - Units
    - Cm / Kg
    - Inch / Pound
  - Page Format
  - Mains filter
    - 50 Hz
    - 60 Hz
  - Display
    - Brightness
    - Contrast

- *Tools*
  - About
  - Print Profile
  - Default Configuration
  - Self-test
    - User
      - Display

- Keyboard
- Printer
- Memory
- About

- Service
  - Not Available

3.3 Menu-activated operation and personalization of the electrocardiograph

Listed below are the operating and configuration details associated with the single items of the menu. To operate the menu refer to the heading "*How to access the menu*".

"Personalise mode" ☑

The menu allows one of the enabled modes to be added to the direct selection of traditional operating modes (Automatic and Manual). The selected mode is indicated in the main page of the display at the top left .

Options / Actions available	Description
☑ Paper saving	The ECG trace is recorded and saved without any hard copy of the signal generated. The steps and the quality of the recording are monitored through messages in the display, the recording can be printed or saved to PC archive. Feature associated with "memory" option.
☑ PC-ECG	The twelve ECG leads are displayed in real time on your Computer screen where, thanks to the CARDIOLINE software it is possible to perform all the ECG recording operations.
☑ Arrhythmia Monitor	The ECG signal is acquired in continuous mode and then printed in compressed format. Any arrhythmic phenomena are highlighted on the trace.
☑ HRV analysis	The signal is acquired and then reprocessed, indicating the parameters and trends of the variation in heart rate.
ECG autotimer	ECGs are recorded automatically at user-defined intervals in "Settings" menu .

The "ECG archive" ☑

The menu allows the main archive management functions to be operated.

Options / Actions available	Description
View	Displays the ECG list contained in the archive. Scroll the list and select an exam/patient. The user can now: 1. Archive the selected exam to a Personal Computer ("ArchPC"); 2. Print the selected example ("Print"); 3. Delete the exam selected ("Delete").
PC archive	Transfers and saves all stored exams to PC.
Print list	Prints the list of exams currently in the memory.
Empty	Deletes all exams held in the memory. A confirmation message is displayed.

"Settings"

The "Settings" menu allows different users to configure the functions of the electrocardiograph as best suits their individual working methods. Configurable properties are grouped together into two menus: "Operation Profile" and "General".

"Operation Profile"

Options / Actions available	Description
Patient data management	The method of managing patient data can be selected by the user. The selected data will be requested at the start of each recording. Select "All/None" to cancel the request or enable the complete list. o All / None (to quickly select or de-select all available data). o Patient ID o Name o Last Name o Last Name 2 o Date of Birth o Sex o Height o Weight o Type o Blood Pressure o Medications o Notes o Ward/Dept. (to modify the reference entered in the settings phase for the current ECG only)

Lead Sequence	Leads sequence. The sequence of leads printed can be selected. As well as modifying the order in which the leads are printed out, the selection also influences the rhythm lead selection menu. Two options are available: 1. Standard; 2. Cabrera.
Auto FP	The way the signal is represented may also be selected when a "Full Page" format is selected Two options are available: 1. “simultaneous” all 12 leads of the 3x4 part have the same time reference; 2. “sequential”: the 12 leads of the 3x4 part are represented in time sequence.
FP Rhythm Leads	The reference leads can be set for rhythm in FP formats (3x4+R and 3x4+3R).
☑ Analysis configuration	The type of processing of the ECG trace acquired in automatic mode can be selected. The choice influences the type of document printed. Two configuration menus are available, linked to the type of automatic processing available: "ECG Parameters" and "ECG Interpretation". Processing may also be disabled by selecting "None". ➢ "ECG Parameters". o "Summary" represents the minimum report and cannot be de-selected. The following are reported: date and time of recording, patient data, note field, main ECG parameters calculated (heart rate; rhythm type; P, QT, QTc, PR, QRS and QTr wave amplitudes; frontal vectors; axes). o "ST Parameters" printout of table of ST depression values on the twelve leads. o “Templates”: printout of templates relative to the twelve leads. ➢ "ECG Interpretation". o "Summary" represents the minimum report and cannot be de-selected. The following are reported: date and time of recording, patient data, note field, ECG parameters calculated, frontal vector, indication of normality. o “Rhythm Analysis”: print rhythm strip and diagnosis. o "Interpretation" processing and printing out of ECG interpretation. In particular: atrial diagnosis, repolarisation disorders, atrial blocks, QRS-T evaluation. o "Parameters" print complete ECG parameters table. o “Templates”: printout of templates relative to the twelve leads.
Configure Copy	The "Copy" key can be configured. 1. “Complete”: the last automatic recording is printed out in full.

	2. "ECG only": only ECG of last automatic recording is printed out. 3. “Analysis only”: only analysis of last automatic recording is printed out (if available).
☑ PC archive	The "PC Archive" function enables the trace recorded and stored automatically to be transferred to a PC, using CARDIOLINE software. The functions of the copy key change according to the choice made. 1. "Copy to PC" when the copy key is pressed, the past automatic recording is transferred to the PC. 2. "Hard copy" pressing the copy key, the last recording is printed out on paper.
☑ Archive management	The way in which ECG traces are saved can be set, and the memory status checked. ➢ "Save" o "Automatic" trace saved automatically after acquisition without action by operator The operation is indicated on the display by the following messages: "Saving...." and "ECG saved". o "On Demand". when recording is complete, confirm save request displayed. "Save ECG?" Press OK to continue. o "None" saving disabled. ➢ "Delete" o "Manual" files can be deleted using the delete function on the Look in ECG archive menu. o "Automatic" archive files are deleted automatically after successful transmission to a PC with the ArchPC function.
☑ HRV analysis	The following can be set: duration of the test (1 to 5 minutes) and reference lead for analysis.
ECG Autotimer	The following can be set: number of recordings (intervals); duration of intervals (i.e. time between recordings); number of leads being printed: twelve (in format set), three or six (selectable).
Arrhythmia	The user can set: - the RR advance (in percentage); - the RR delay (in percentage); - the Print Advance: how many seconds of signal to be printed as reference normal ECG before the first event (min 2 sec. max 10 sec.); - the Print Delay: how many seconds of normal ECG after the last event (min 2 sec. max 10 sec.); - Arrhythmia monitor: enable the printout of the abnormal ECG during the test.

"General".

Options / Actions available	Description
User Name	The user ID data can also be entered and reproduced on all printed documents. Space available 30 characters.
Device ID	An item identifying the device being used can be entered.
Ward/Dept. name	The name of the Ward/Dept. performing the recording can be entered. The name entered can be changed before a recording enabling the "Ward/Dept." request in the patient data settings.
Date \ Time	Accessing the date/time programming masks. Use number keys for settings.
Units	Set units to be used for management of numerical patient data (Weight and Height).
Page format	Set reference page format (UNI A4 or Letter).
a.c. mains filter	To ensure the device operates correctly select the mains frequency in the area of use. Two options are available: 50 Hz, 60 Hz.
Display	"Brightness" and "Contract" may be set according to the environmental conditions of use.

"Tools"

The "Tools" menu allows the user to access system related information and activate the self-test and setting functions of the device.

Options / Actions available	Description
About	Displays the version of software program installed.
Print Profile	To print out the operation profile set.
Default Configuration	To restore the ECG to factory configuration, cancelling the settings selected.
Self-test	There are two self-test menus available: "User" and "Service". Do not run the service self-test without a qualified technician in attendance. For details, see "Maintenance".

4 Preparing for an ECG recording

This section describes the preliminary operations required when recording an at-rest electrocardiogram with the **CARDIOLINE® ar2100adv** electrocardiograph. In particular, indications are given for "*connecting the patient cable*", "*preparing the patient*", "*applying the electrodes*". Also illustrated are the necessary procedures for choosing the correct recording parameters, such as "*speed, sensitivity and activation of filters*".

4.1 Connecting the patient cable

Connect the terminal plug of the patient cable to the connector identified with the symbol , positioned on the right side of the device.

Note: *to avoid breaking the patient cable, remove it from the connector gripping it by the plug, and without tugging.*

Warning: *the device is protected internally against defibrillation discharges; restoration of the signal is guaranteed as long as original electrodes are used. To ensure conditions of safety are always maintained, use only original accessories.*

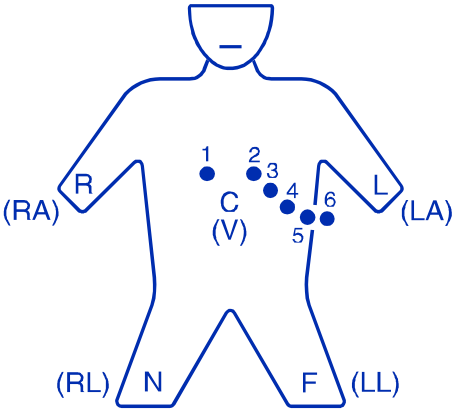
4.2 Preparing the patient and applying the electrodes

Careful preparation of the patient and correct positioning of the electrodes are fundamental in obtaining an ECG recording of high quality.

- ✓ First, make sure the patient is comfortable and relaxed and does not feel cold. The individual should lie back on a suitably large couch with arms and hands extended along the sides of the body: this will minimise the likelihood of the ECG trace being affected by muscle tremor.
- ✓ Clean the skin thoroughly with alcohol or ether at the areas where the electrodes will be placed.
- ✓ Connect each colour-coded plug of the patient cable to the respective electrode, observing the colour-position matches indicated below:

Colour	*Symbol*	*Electrode position*
Red	R	Right arm
Yellow	L	left arm
Green	F	Left leg
Black	N	Right leg
White - Red	C1	V1
White - Yellow	C2	V2
White - Green	C3	V3
White - Brown	C4	V4
White - Black	C5	V5
White - Violet	C6	V6

- ✓ Apply a small amount of electrocardiograph conductive gel to the area of the skin that will be in contact with the electrode, spreading it carefully and evenly (this is not necessary when using disposable electrodes with built-in gel).
- ✓ The following figure shows the standard positioning of the electrodes.



Standard positioning of the electrodes

V1: on the 4th intercostal space, right parasternal;

V2: on the 4th intercostal space, left parasternal;

V3: on the 5th rib, between V2 and V4;

V4: on the 5th intercostal space, left hemiclavicular;

V5: on the left anterior axillary, same level as V4;

V6: on the left mid-axillary at the level of V4;

Peripheral electrodes: generally a few centimetres above ankles and wrists.

Warning: *make certain that the conductive parts of the electrodes are not in contact one with another or with other metallic parts. In any event, silver and silver chloride electrodes are designed and manufactured in such away as to minimise the likelihood of accidental contact between conductive parts and external metal objects. Ensure that the device is not affected by disturbances originating from the a.c. mains power supply (see "Initial preparation").*

4.3 Select recording characteristics operating mode, print format, speed, sensitivity, filters

Operating mode

The available recording modes (Operating mode) depend on the active configuration of the electrocardiograph.

to select the desired mode; the corresponding choice is displayed on the screen. The options available are: Automatic, Manual, Personalised. To change Personalised mode see "Settings".

During printing, the active mode is printed on the information line of the printout.

Options / Actions available	Description
Automatic ECG	All 12 ECG leads are recorded simultaneously (10 seconds). The signal printed out refers to the same time period, and is saved.
Manual ECG	The selected leads are recorded and printed out. The recorded signal is in real time, i.e. the trace is produced simultaneously with its acquisition.
Personalised	See “Personalised mode” for details.

Print format

Several print formats are available, according to the operating mode selected.

to select the desired format; the corresponding choice is displayed on the screen.

The available formats are as follows:

Format Type	Description
3	In "Manual" mode: three leads per page continuously.
6	In "Manual" mode: six leads per page continuously.
12	In "Automatic" mode: the twelve ECG leads are printed on a single Total page. pages per ECG: 1. Additional pages if diagnosis aids (e.g. Interpretation) are available. In "Manual" mode: twelve leads per page continuously.
3x1	In "Automatic" mode: the twelve ECG leads are printed out in groups of three; each page presents two groups. Total no. of pages per ECG: 2. Additional pages if diagnosis aids (e.g. Interpretation) are available.
3x2	In "Automatic" mode: the twelve ECG leads are printed out in groups of three; each page presents two groups. Total no. of pages per ECG: 4. Additional pages if diagnosis aids (e.g. Interpretation) are available.
6x1	In "Automatic" mode: the twelve ECG leads are printed out in groups of six per page and each page presents two groups. Total no. of pages per ECG: 1. Additional pages if diagnosis aids (e.g. Interpretation) are available.
6x2	In "Automatic" mode: the twelve ECG leads are printed in groups of six on a single page. Total no. of pages per ECG: 2. Additional pages if diagnosis aids (e.g. Interpretation) are available.

Full Page 1 (3x4+R) Full Page 3 (3x4+R)	In "Automatic" mode: the twelve ECG leads are printed on a single page: 2.5 secs for each lead (3x4) plus 10 secs for the rhythm leads (up to 3, selected by the user in FP3). The upper part of the page reports the diagnosis summary (if available). Total no. pages: 1. Additional pages if extended diagnosis aids (e.g. Interpretation) available.

The selected format will be applied to all manual, automatic and autotimed twelve lead recordings.

Speed of recording on paper

to select the speed; the corresponding value appears in the display. The options available are: 5mm/s, 25 mm/s and 50 mm/s.

During printing, the paper transport speed is indicated on the information line.

Sensitivity of recording on paper

to select the sensitivity; the corresponding value appears in the display. The options available are: , 5 mm/mV, 10 mm/mV and 20 mm/mV.

During printing, the recording sensitivity is indicated on the information line.

Note: *selecting the sensitivity is set automatically by the device in a way that optimises the recording over the entire width of the paper. In this case, a sensitivity of 2.5 mm/mV may be used. This option is recommended for multi-channel printing. To find out how automatic sensitivity is determined, see "Technical Specifications".*

Recording filters

If necessary, it is possible to activate filters capable of improving the legibility of the signal without modifying its morphology. Activation of the filters has an effect on the printed signal. To guarantee a correct and accurate analysis, any automatic interpretation of the trace is performed always and only on the non-filtered ECG signal.

to activate the filters; the corresponding symbol appears in the display. The filters available have been designed to reduce the effect of both mains disturbances and muscle tremor.

The special isoelectric anti drift filter (ADF) remains permanently activated.

During printing, the activated filters are indicated on the information line.

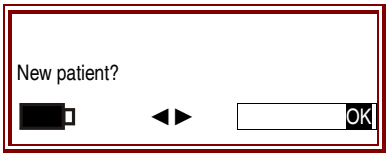
Warning: *the filters of your ECG are very effective in attenuating disturbances and do not reduce the diagnostic content of the traces. Nonetheless, it is advisable to eliminate the cause of the interference and not only the visible effect on the trace (see "Troubleshooting"; "Initial preparation").*

5 Recording of a rest ECG

5.1 Patient data entry

At the beginning of each recording, in case you have choose to insert patient data, except in the case of "PC ECG" mode, the patient data management pages are displayed.

Phase 1: select type of patient



- to clear data relative to the previous recording and begin a new entry.
- to display the "View" option.
- to scroll through existing data and confirm:
- Esc to confirm without modification.

Phase 2: enter data

The display prompts, in sequence, for "Patient ID", "First name", "Last name 1", Last name 2 "Date of birth", "Sex", "Height", "Weight", "Type", "Blood Pressure", "Medications", "Notes", "Ward/Dept."

- 1 Q … 3 E to enter data.
- X to delete the character highlighted by the cursor.
- to change the position of the cursor and select the "Sex" of the patient.
- to start the recording without patient data (if you have chosen the option "new patient") or with the previous data (if you have chosen the "option View").

- to terminate the data entry step, the recording is cancelled.

Warning: *new data will be saved only when the final item entered is confirmed.*

5.2 Recording in manual mode

Having selected "manual" mode (see "*Operating mode*"):

- to start the recording. If the signal has not yet been initialised, the ⚠ symbol will be displayed.
- If predict, the patient data entry procedure now starts (see "*Patient data entry*").
- to change the leads printed during recording. The names of the active leads are indicated in the display.
- to interrupt the recording (stop).

Note: *during a manual recording, it is possible to change the recording characteristics: speed, sensitivity, filters.*

Warning: *starting a manual recording cancels the last trace recorded in automatic mode.*

5.3 Recording in automatic mode

An automatic recording allows the user to run available computation and analysis programs on the traces (" ECG Parameters", " ECG Interpretation" options), to obtain a copy of the recording, to save the recording ("Memory" option), and to transfer the ECG to a Computer ("PC archive" option).

Having selected "Automatic" mode (see "*Operating mode*"):

- to start the recording. If the signal has not yet been initialised, the message "Wait …" will be displayed.
- The patient data entry procedure now starts (see "*Patient data entry*").
- During the recording, progress messages are displayed: 1. "Acquisition …"; 2. "Acquisition OK". The patient can now be disconnected.

to interrupt printing (stop). If the signal has already been saved ("Acquisition OK") it will still be possible to print a copy of the recording.

Automatic calculation of ECG parameters

The program for automatic measurement of the ECG parameters allows a report of the principal parameters calculated to be obtained at the end of each automatic recording.

- *Start:* automatic at the end of the recording.
- *Stop:* automatic at the end of printing the report. The message "Analysis OK" is displayed.

The principal items of information in the report are:

- computed value of the following parameters: heart rate; rhythm type; P, QT, QTc, PR, QRS and QTr wave amplitudes, frontal vectors, axes.
- summary table of ST amplitudes relative to all twelve leads ;
- templates of all twelve leads .

Warning: *if the parameters cannot be computed, the message "Analysis nd" is displayed. This situation may be due to excessive noise affecting the ECG trace or to incorrect positioning of the electrodes.*

Automatic ECG interpretation

The automatic ECG interpreter is a function of the analysis program that can be used to obtain an evaluation at the end of each automatic recording.

- *Start:* automatic at the end of the recording.
- *Stop:* automatic at the end of printing the report. The message "Analysis OK" is displayed.

Warning: *The automatic interpretation program in case of missing patient data, considers for the analysis a person of 35 years old gender male.*

Warning: *the computerised analysis must always be validated by the medical specialist responsible for the ECG examination.*

Warning: *if the device cannot perform the analysis due to poor signal quality the following error message appears on the display: "Analysis na" This situation may be due to excessive noise affecting the ECG trace or to incorrect positioning of the electrodes.*

Note: *The ECG interpreter program is structured in four parts:*

1) processing and filtering of the electrocardiographic signal

2) identification of the waveform and positioning of the markers

3) calculation of the characteristic parameters of the QRST complex

4) processing of the diagnosis and analysis of the rhythm.

The part of the program "processing of the diagnosis and analysis of the rhythm", provides the evaluation of the trace, and specifically:

a) identification of the parameters that deviate from standard (these parameters are identified in the final document by an asterisk), for example, duration of P wave, lengthening of PQ interval, widening of QRS. Furthermore, the data related to the rhythm is analysed and evaluated and the related indications are given, for example sinus arrhythmia, sinus rhythm with extra ventricular systole with compensatory pause, etc. All diagnostic indications described are defined category B, in accordance with American College of Cardiology conventions;

b) analysis of repolarisation changes, as internal or external, and the degree of intensity as reflected by variations in the ST-T segment. These diagnostic indications are defined category;

c) In the EKG program, the category A diagnostic suggestions are obtained using a multivariate alternative classification, that is a combination of statistical analysis and a ramified structure decisional technique. By virtue of its characteristics and the reliability of the results provided, the EKG program is in conformity with the requirements of IEC standards pertinent to programs for the automatic ECG trace evaluation.

Copy of an automatic ECG recording

An ECG recorded in automatic mode, and computed ECG parameters if any, are automatically saved and can therefore be reproduced on paper any number of times.

to start printing a copy. The message "Copying …" is displayed.

to interrupt printing (stop).

If the memory does not contain valid data, the message "No data" is displayed.

Note: *the trace is saved without filtering the signal, irrespective of whether the filters are activated during the recording. The parameters can therefore be modified before printing: filters, speed and sensitivity.*

Warning:

If the "Memory Option" is not installed*: each new acquisition cancels the ECG trace saved previously!*

If the "Memory Option" is installed: *the save procedure is related to the set-up. After switching off the unit, enter the archive to obtain copy of the ECG recorded.*

ECG memory: saving a recording

At the end of the automatic recording the ECG may be saved in the memory. The archive can contain up to 40 recordings for subsequent processing or transfer to PC ("Memory option").

- *Start:* automatic, or on demand at the end of a recording (see "*Settings*").

Warning: *The message "Memory full" is displayed when the memory space is closed to be completely filled. After finishing the current operation, free space in the memory by cancelling exams or transferring the archive to the PC.*

ECG memory: archive management

Having selected "ECG Archive":

- to select the menu: 1. View; 2. PC Archive; 3. Print List; 4.Empty.
- to confirm the menu.

For details of the options available, see "ECG Archive".

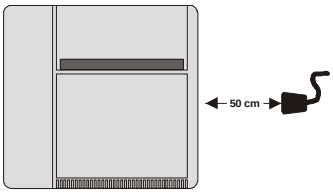
Saving to Personal Computer archive

Warning: *to ensure correct data transmission, position the IR adapter of the PC at a distance of no more than 50cm. Avoid placing objects between the two interfaces.*

Your electrocardiograph is capable of transferring stored ECG traces to a Personal Computer equipped with CARDIOLINE management software. For details on the use of the application software, consult the specific manual.

If the "Memory Option" is not installed:

- Position the electrocardiograph relative to the infrared adapter (connected previously to the PC) as illustrated in the following figure:



- plus to start the transfer.

If the "Memory Option" is installed:

The user can either proceed as described above, if the intention is to transfer the complete ECG archive.

A detailed management of the ECG transmission can be done by using the "ECG archive" menu.

- Position the electrocardiograph as indicated previously.
- Select the "ECG archive" menu and proceed as appropriate. For details of the options available, see "*ECG archive*".

5.4 Recording in ECG Autotimer mode

Warning: *To obtain a correct recording in "ECG Autotimer" mode, ensure that the battery and paper load are enough to perform the selected acquisition.*

Operating in Autotimer mode, the device can make timed recordings of the 12 standard leads or of a group of three user-selectable leads.

After having selected "ECG Autotimer" mode:

- to start the recording the message "Paper, Battery!" will appear. If the signal has not yet been initialised, the message "Wait …" will be displayed.
- If predict, the patient data entry procedure now starts (see "*Patient data entry*").
- The programmed recordings are in real time . The printouts shown information, alongside the date / time field, relating to the number of the interval and the time of recording (format: #xx yy min).
- to start a recording manually within an interval.

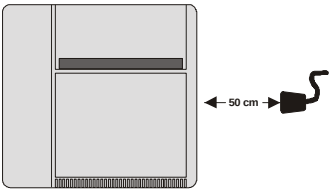
to interrupt (stop).

5.5 Recording in "PC ECG" mode

Your **ar2100adv** becomes a PC-based acquisition system. For details on the use of the application software, consult the specific manual.

Having selected "PC ECG" mode (see "*Operating mode*"):

- Position the electrocardiograph relative to the infrared adapter (connected previously to the PC) as illustrated in the following figure:



- to start transmission. The message "PC ECG transmission…" is displayed.
- to end transmission.

Warning: *to ensure correct data transmission, position the IR adapter of the PC at a distance of no more than 50cm. Avoid placing objects between the two interfaces.*

5.6 "Paper Saving" mode"

If "Paper Saving" mode is selected the device performs and stores an automatic ECG recording including any ECG calculation and analysis programs (option "ECG Parameters", "ECG Interpretation") without any printout.

After selecting "Paper Saving" mode (see "Operating mode"):

- to start the recording. If the signal has not yet been initialised, the message "Wait …" will be displayed.
- If predict, the patient data entry procedure now starts (see "*Patient data entry*").
- During the recording, progress messages are displayed: 1. "Acquisition …"; 2. "Wait….." while the analysis is being performed

(the patient can now be disconnected) 3. "Save…".

- Once the ECG has been stored it can be printed or transferred to a PC from the "ECG archive" function.

5.7 Recording in "HRV Analysis" mode

Warning: *To obtain a correct recording in "HRV Analysis" mode, ensure that the battery and paper load are enough to perform the selected acquisition.*

A recording in HRV mode allow to analyse the measurement of the heart rate variability in a predicted interval (from 1 to 5 minutes) and to printout a complete report: full disclosure of the reference ECG lead (selected by the menu), patient data summary, table of the variability parameters (total R-R intervals, medium HR, medium R-R interval, maximum R-R interval, minimum R-R interval, ratio max/min., standard deviation, coefficient of R-R variability, number of R-R intervals greater than 2.2s and not reported on the graph) graph of the R-R distribution in the time domain, R-R trend graph.

Note: *only the electrodes referred to the lead set for the test can be connected, improving patient comfort.*

After selecting "HRV Analysis" mode:

- To start the recording, the message "Paper, Battery!" will appear. If the signal has not yet been initialised, the message "Wait …" will be displayed.
- If predict, the patient data entry procedure now starts (see "*Patient data entry*").
- The display shows the time from the test start. *The test is automatically terminated at the end of the scheduled time and the final report is printed out.*
- to interrupt (stop). *No report is printed and the recorded data are cancelled.*
- to print copy of the report at the end of the test.

5.8 Recording in "Arrhythmia mode"

Warning*: To obtain a correct recording in "Arrhythmia mode" mode, ensure that the battery and paper load are enough to perform the selected acquisition.*

A recording in Arrhythmia mode allow to analyze in real time the ECG signal

for a predicted period of time in order to detect potential abnormalities of the Rhythm in the time domain.

During the test if an abnormal rhythm is detected a printout of the events can be obtained in continuous until the rhythm become normal again (the length of the printout depends on the setup). At the end of the test, or after every 5 minutes, a complete report is printed: full disclosure of the reference ECG lead (selected by the menu) with marker identification of the abnormal beats (*), patient data summary, table of the computed parameters.

Note: connect only the electrodes related to the reference lead in order to increase the patient comfort.

After selecting "Arrhythmia mode":

- To start the recording, the message "Paper, Battery!" will appear. If the signal has not yet been initialised, the message "Wait …" will be displayed.
- The patient data entry procedure now starts, if predict (see "Patient data entry").
- Pressing again the key after choosing "new patient", the recording start without entry the data patient.
- The display shows the time from the test start. The test is automatically terminated at the end of the scheduled time and the final report is printed out (in any case every 5 minutes if the test is longer than it).
- to interrupt (stop)

5.9 Defibrillation!

If defibrillation occurs the ⚠ symbol is displayed. Within 10 seconds of the discharge the signal is automatically restored (if a printout of the signal was active in manual mode).

Remember always to avoid direct contact between the electrodes of the defibrillator and those of the electrocardiograph. The original approved electrodes supplied with the electrocardiograph have been designed so as to minimise the risk in case of accidental contact.

6 Management and control of electrocardiograph functionalities

6.1 Disconnected electrodes, potential defibrillation

Saturation events are controlled and monitored by your electrocardiograph. The response of the electrocardiograph depends on the current phase of operation.

Stop phase

- ✓ *Symbol* ⚠ *displayed*: critical electrode contact. The user can proceed with the recording; the "critical" electrodes are indicated in the print report on the information line (for example "⚠ L 1" indicates the critical nature of the left arm electrode and of electrode C1).
- ✓ *Symbol* ***OL*** *displayed*: electrodes disconnected (saturation). It is not possible to start an automatic recording. A manual recording can be started; the "disconnected" electrodes are indicated in the display and in the print report on the information line, and a flat signal will be reproduced on paper where a lead cannot be acquired due to the absence of an electrode (e.g. "***OL*** L 1" indicates saturation of the left arm electrode and of electrode C1).

Manual recording phase

The event is indicated as for the stop phase. When normal conditions have been restored, the signal is centred.

Automatic recording phase

If the event is detected during acquisition (10s), the ECG is stopped and automatically returns to the stop phase. If the signal is already buffered, the print continues without interruption. The event is indicated in the same way as for all other phases.

Defibrillation

The ⚠ symbol is displayed. See "Defibrillation".

6.2 Batteries low or in need of recharging

When the symbol is displayed the battery must be recharged. the reserve charge is lower than 30%.

Follow the indications given in the heading "*Installation and initial preparation*".

6.3 Print system control. Out of paper

Sensors verify the correct closure of the paper compartment cover and indicate when the thermal paper is depleted. During a recording, printout is inhibited automatically and the messages "Out of paper" or "Printer!" are displayed for 3 seconds approx.

6.4 Status messages and error indication: description and related event

Listed below are the various error messages displayed and/or printed on paper when abnormal events occur. Each message is correlated to a specific condition or phase of operation.

Messages

Message	***Description of status / event***
Not Available!	Function or action not available for the selected operating mode
Analysis na	Automatic ECG analysis cannot be performed due to excessive signal noise
No data!	Impossible to obtain copy of the last recording
⚠	- Critical electrodes - Waiting for signal to be centred before printing can start
OL	Disconnected electrodes or potential defibrillation
Out of paper!	Paper finished, insert a new pack / roll
Printer!	Paper compartment cover open or not properly closed
	Batteries low
	Batteries completely discharged

6.5 Troubleshooting

The following table summarises certain problems that may occur and the relative causes.

Problem	***Cause***
Isoelectric line drift	- Use of electrodes other than originals Use of electrodes in saturation - Insufficient electrode/skin contact - Electrode surface dirty - Patient moving
Interference from a.c. mains supply	- Voltage generator too close; presence of other clinical instruments (e.g. X-rays, etc.) - Patient in contact with metallic parts or with other persons
Muscle tremors	- Patient not relaxed - Peripheral electrodes adhering too tightly
Irregular paper transport	- End of paper roll - Paper roll incorrectly positioned - Use of non-original paper
Analysis impossible	Signal too unstable or noisy
No copy of trace	Recording interrupted before 10 seconds have elapsed
Abnormal signal	- Defective patient cable - Defective electrodes

7 Maintenance

7.1 Self-test

Run the User self-test procedure periodically. This performs a routine check on the functional efficiency of the display, the keys, the writing system and the memory. The user can also print out identifying information relative to the individual device.

In the event of error messages being displayed, contact the **CARDIOLINE®** Authorised Assistance Centre, and a technician will investigate and eliminate the causes of the trouble.

The self-test menu is accessed by selecting "Tools" -> "Self-test" -> "User". Before running the self-test procedure, ensure that there is paper loaded.

- to select the type of test required.
- to start the test.
- Tests available:
  - Display: pixel scan. The presence of blank areas signifies faulty operation of the display.
  - Keyboard: the position of the single keys is simulated in the display. Pressing a given key, the corresponding area of the display is energised. A lack of response in any one area indicates that the relative key is faulty.
  - Printer: the writing system generates two triangular waves, the character set in the memory, and signals with different speeds and sensitivities. Irregularities of the printing system are detectable in non-continuous lines.
  - Memory: a message relating to the status of the memory is printed.
  - About. The following items of information are printed: model identification, serial number of the device, details of software, version and language code.

Warning: *do not run the service self-test without a qualified technician in attendance.*

7.2 Replacing the thermal paper

When the thermal paper is depleted, the device stops and any attempt to start recording is inhibited (see "*Print system control.* "*Out of paper*".)

To replace the paper, proceed as indicated in the heading "*Installation and initial preparation*".

7.3 How to clean the device and the electrodes

To clean the device, use a cloth moistened with water or denatured ethyl alcohol. Do not use other chemical products or household detergents.

For the electrodes: remove the electrodes from the patient cable and wash under running water. Do not scratch the electrodes and do not wash the leads box and the patient socket.

Note: *the device cannot be sterilised! The electrodes can be sterilised with ethylene oxide.*

7.4 Periodic checks

To ensure correct and long-lasting operation of the device, it is necessary to have an Authorised Assistance Centre carry out the following checks:

- ✓ paper drive speed calibration: every year;
- ✓ cleaning of paper compartment, paper presence sensor and writing system: every year;
- ✓ integrity of cables and connectors: every year, by means of an ECG simulator;
- ✓ general check of functional efficiency of the device and leakage currents: every 2 years.Technical information

Technical information

et medical devices SpA undertakes, when requested by qualified persons, to furnish the circuit diagrams and the list of components used in the device, and the information necessary to repair the parts of the device considered serviceable.

8 Technical specifications

A.c. mains power supply	A.C. mains with external power supply 230 V ± 10% 50/60Hz 115 V ± 10% 50/60 Hz
Maximum current absorbed	0.5 mA at 115 V ~ ±10% 0.25 mA at 230 V ~ ±10%
Mains protection	Fuse: T 0.5 A
Internal power source	12 V - 2Ah rechargeable lead battery
Internal power supply protection	Pico fuse SHF SLO-BLO T 5 A Littelfuse
Applied part	CF type
Defibrillation protection	Internal
Input dynamic	± 300 mV @ 0 Hz.± 10 mV in pass band
Input impedance	> 100 MΩ on each electrode
Common mode rejection	> 100 dB
Frequency response	0.05 - 150 Hz (-3dB)
Time constant	3.3 s
Acquisition	12 bit 1000 samples/s/channel printing and filters 500 samples/s/channel in calculation and filters Resolution 5 μV/bit
Leads	12 Standard or Cabrera leads
Signal memory	10 seconds for each lead in automatic mode
Recording sensitivity	5 – 10 – 20 mm/mV
Monitor	Backlit graphic display 120x32 pixels, (61x16 mm), 2,5 inches
Writing system	Thermal printer, 8 dot/mm Usable print height 210 mm
Print channels	12
Print format	Automatic mode: 3, 6x1, 6x2, Full Page (3x4+R)x1, 12x1 Manual mode: 3, 6, 12
Paper transport speed	5 mm/s ± 10% 5 - 25 – 50 mm/s
Thermal paper	*in rolls*: length 17 m, page 210x280, gridded. *Z-fold pack:* length 30 m, page 210x150 mm, gridded.
Pacemaker recognition	Recognises pulse in accordance with current IEC standards
Filters	*Mains interference:* Modified digital notch filter 50 - 60 Hz *Anti-drift:* Digital high-pass 0.5 Hz, linear phase
Serial interface	Infrared
Keyboard	Membrane with functional and alphanumeric keyboard extended
Interpretation program	Parameter calculation (optional) *ECG interpretation* (optional): Arrhythmia Program (optional) HRV: RR variability (optional)
Type of use	Continuous
Operating modes	*Manual:* acquisition and printing in real time *Automatic* : simultaneous acquisition *Timed:* acquisition at user-defined intervals

	Arrhythmia: arrhythmic event recognition (optional) *PC-ECG:* real time acquisition with display at PC *HRV*: heart rate variability analysis *Paper Saving*: Automatic acquisition and archiving without printing
Battery capacity	*Internal battery:* 1hour with printing in 6 channel mode
Recharging time	*Internal battery:* 24 hours 100%
Housing protection category	IP 20
Ambient conditions: - operation	 *Ambient temperature:* from +10°C to +40°C *Relative humidity:* from 25% to 95% (without condensation) *Atmospheric pressure:* from 700hPa to 1060 hPa
- transport and storage	*Ambient temperature:* from -10°C to +40°C *Relative humidity:* from 10% to 95% (without condensation) *Atmospheric pressure:* from 500 to 1060 hPa
Dimensions	325 x 80 x 345 mm (length x height x depth)
Weight	4800 grams without paper
Conformity to standards	EN 60601-1: 1990 EN 60601-1/A1: 1992 EN 60601-1/A2: 1995 EN 60601-1/A13: 1995 *General standards for safety of electromedical equipment* EN 60601-1-2: 1993 *Standards on electromagnetic compatibility of electromedical equipment* EN 60601-2-25: 1995 EN 60601-2-25/A1: 1999 *Particular safety standards for electrocardiographs* EN 60601-2-51/Ed.1: 2001 *Particular standards on essential recording and analysis performance safety of single and multichannel electrocardiographs.*

Basic accessories supplied

- Patient cable ref. 63050025
- 6 suction cup electrodes ref. 66030163
- 4 peripheral electrodes ref. 63030105
- Bottle gel ref.66020002
- 1 pack Z-fold paper 210mm x 150mm x 30 metres ref. 66010027
- ECG ruler
- User manual

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